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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,499	02/08/2002	Neil M. Wolfman	8702.0100-00	3454

7590 05/20/2003

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/071,499

Applicant(s)

WOLFMAN ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-118 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to GDF-8 polypeptides, classified in class 530, subclass 350.
- II. Claims 21-37, drawn to GDF-8 polynucleotides and means of expression, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.
- III. Claims 38-59, drawn to methods of treatment with GDF-8 polypeptides, classified in class 424, subclass 198.1.
- IV. Claims 60-79 and 90, drawn to BMP-11 polypeptides, classified in class 530, subclass 350.
- V. Claims 80-89 and 91-96, drawn to BMP-11 polynucleotides and means of expression, classified in class 435, subclasses 69.1, 320.1, and 325, and class 536, subclass 23.5.
- VI. Claims 97-118, drawn to methods of treatment with BMP-11 polypeptides, classified in class 424, subclass 198.1.

The inventions are distinct, each from the other because of the following reasons:

The polypeptides of Invention I are not related to the polynucleotides of Invention II. They differ structurally and functionally, cannot be used together or interchangeably, and have non-coextensive searches and considerations.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention I have different uses, such as the generation of antibodies, and the diseases of Invention III can be treated in other ways, such as with small molecules.

The polypeptides of Invention I are not related to the polypeptides of Invention IV. They differ structurally and functionally and have non-coextensive searches and considerations.

The polypeptides of Invention I are not related to the polynucleotides of Invention V. They differ structurally and functionally, cannot be used together or interchangeably, and have non-coextensive searches and considerations.

The polypeptides of Invention I are not related to the methods of Invention VI. They cannot be used in these methods.

The polynucleotides of Invention II are not related to the methods of Invention III. They cannot be used in these methods.

The polynucleotides of Invention II are not related to the polypeptides of Invention IV. They differ structurally and functionally, cannot be used together or interchangeably, and have non-coextensive searches and considerations.

The polynucleotides of Invention II are not related to the polynucleotides of Invention V. They differ structurally and functionally and have non-coextensive searches and considerations.

The polynucleotides of Invention II are not related to the methods of Invention VI. They cannot be used in these methods.

The methods of Invention III are not related to the polypeptides of Invention IV. The polypeptides cannot be used in the methods.

The methods of Invention III are not related to the polynucleotides of Invention V. The polypeptides cannot be used in the methods.

The methods of Invention III are not related to the methods of Invention VI. They require different reagents and have different goals.

The polypeptides of Invention IV are not related to the polynucleotides of Invention V. They differ structurally and functionally, cannot be used together or interchangeably, and have non-coextensive searches and considerations.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Invention IV have different uses, such as the generation of antibodies, and the diseases of Invention VI can be treated in other ways, such as with small molecules.

The polynucleotides of Invention V are not related to the methods of Invention VI. The polynucleotides cannot be used in the methods.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the searches required the different groups are different, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

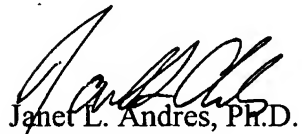
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres, whose telephone number is 703-305-0557. The examiner can normally be reached on 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Janet L. Andres, Ph.D.  
Patent Examiner

May 19, 2003